ENDORSEMENT ON ORIGINATING PLEADING OR PETITION FOR SERVICE OUTSIDE BRITISH COLUMBIA

The Plaintiff, Victor Chapdelaine, claims the right to serve this pleading on the Defendants Pur Medical Corporation, Skinrx Distribution Inc., Basis Medical Technologies Inc., Polymekon S.R.L., John McCahill, Allan Ward, Chantal Ward, Universities Dpt. And International Centers of Research on Innovative Materials on the grounds that it (e) concerns contractual obligations performed in British Columbia; (f) concerns restitutionary obligations that arose in British Columbia; (g) concerns a tort committed in British Columbia; and (h) concerns a business carried on in British Columbia.

SUPREME COURT
OF BRITISH COLUMBIA
VANCOUVER REGISTRY

APR 01 2011

S-112152

NO:
VANCOUVER REGISTRY

IN THE SUPREME COURT OF BRITISH COLUMBIA

BETWEEN:

VICTOR CHAPDELAINE

PLAINTIFF

AND:

PUR MEDICAL CORPORATION, SKINRX DISBTRIBUTION INC., BASIS MEDICAL TECHNOLOGIES INC., POLYMEKON S.R.L., JOHN McCAHILL, ALLAN WARD, CHANTAL WARD, UNIVERSITIES DPT. AND INTERNATIONAL CENTERS OF RESEARCH ON INNOVATIVE MATERIALS

DEFENDANTS

Proceeding under the *Class Proceedings Act*, R.S.B.C 1996, c. 50

NOTICE OF CIVIL CLAIM

This action has been started by the plaintiff(s) for the relief set out in Part 2 below.

If you intend to respond to this action, you or your lawyer must

(a) file a response to civil claim in Form 2 in the above-named registry of this court within the time for response to civil claim described below, and
(b) serve a copy of the filed response to civil claim on the plaintiff.

If you intend to make a counterclaim, you or your lawyer must:

(a) file a response to civil claim in Form 2 and a counterclaim in Form 3 in the above-named registry of this court within the time for response to civil claim described below, and
(b) serve a copy of the filed response to civil claim and counterclaim on the plaintiff and on any new parties named in the counterclaim.

JUDGMENT MAY BE PRONOUCED AGAINST YOU IF YOU FAIL to file the response to civil claim within the time for response to civil claim described below.

Time for response to civil claim

A response to civil claim must be filed and served on the plaintiff(s),

(a) if you reside anywhere in Canada, within 21 days after the date on which a copy of the filed notice of civil claim was served on you,
(b) if you reside in the United States of America, within 35 days after the date on which a copy of the filed notice of civil claim was served on you,
(c) if you reside elsewhere, within 49 days after the date on which a copy of the filed notice of civil claim was served on you, or
(d) if the time for response to civil claim has been set by order of the court, within that time.

Part 1: STATEMENT OF FACTS

THE PARTIES

1. The plaintiff, Victor Chapdelaine, is disabled and unemployed. He resides in Vancouver, British Columbia.

2. The defendant, Polymekon SRL ("Polymekon") is a corporation with its head office at c/o Cittadella della Ricerca, SS 7 Km 7+300, 72100 Brindisi - Italy. It is in the business of developing, manufacturing and marketing material for implantation in humans.

3. The defendant, Pur Medical Corporation, is An Ontario corporation with its registered office at 3rd Floor, 49 Avenue Road, Toronto, Ontario.

4. The defendant, SkinRx Distribution Inc., is an Ontario corporation with its registered office at #33 – 1736 Orangebrook Court, Pickering, Ontario.

5. The defendant, John McCahill, is a businessperson, director and controlling mind and will of the defendants, Basis Medical Technologies Inc. and Pur Medical Corporation.

6. The defendant, Chantal Ward, is a businessperson, director and controlling mind and will of the defendants, Pur Medical Corporation and SkinRx Distribution Inc..

7. The defendant, Allan Ward, is a businessperson, director and controlling mind and will of the defendants, Pur Medical Corporation and SkinRx Distribution Inc.

8. The defendants, Allan Ward, Chantal Ward and McCahill, are hereinafter referred to as the "Personal Defendants". Their addresses are not known.

9. The defendant, Universities Dpt. and International Centers of Research on Innovative Materials, is a corporation or partnership located in Italy engaged in

research, development and marketing of various products, including Bio-alcamid, whose address is not known to the Plaintiff.

10. At all material times the defendants carried on business jointly throughout Canada. Collectively, the defendants researched, developed, tested, manufactured, marketed, distributed, advertised and sold a medical product called Bio-alcamid as a medical product which was safe and suitable for use in cosmetic surgery (tissue augmentation) throughout Canada.

11. The plaintiff sues on his own behalf and on behalf of all others residents in Canada who have had an implant of Bio-alcamid.

12. The plaintiff pleads that by virtue of the acts and omissions described herein, the defendants are liable in damages to him and to the class and that each defendant is responsible for the acts and omissions of the other defendant for the following reasons:

(a) each was the agent of the other;

(b) each defendant's business was operated so that it was inextricably interwoven with the business of the other defendants as set out above;

(c) each defendant entered into a common advertising and business plan to research, design, test, manufacture, distribute, market and sell Bio-alcamid;

(d) each defendant owed a duty of care to the other and to each class member by virtue of the common business plan to research, design, test, manufacture, distribute, market and sell Bio-alcamid;

(e) the defendants intended that their businesses be run as one global business organization.

BIO-ALCAMID, ITS MARKETING AND RISKS

13. Bio-alcamid is a fluid represented by the defendants to be a permanent "filler" injected under the skin to augment areas of tissue loss caused by aging, surgery or disease. In the case of tissue loss or wrinkling caused by aging it is designed to fill out lines and other defects to give the recipient a younger look. One of its main uses has been to alleviate the visual effect of lipoatrophy, which is the loss of fat in the face (or "facial wasting"). It is caused by anti-retroviral drugs used to treat HIV infection and AIDS.

14. Bio-alcamid does not treat any health or life threatening condition and is purely a cosmetic product. Bio-alcamid was approved for treatment by Health Canada pursuant to its Special Release Programme in November, 2004 and it received full approval as a medical device in April, 2006.

15. The defendants marketed and advertised Bio-alcamid to the public and to physicians as:

(a) appropriately tested, safe and non-toxic;

(b) not associated with any significant complication;

(c) not subject to migration from the point of implant to other areas;

(d) not subject to development of granulomas;

(e) suitable for use in the indicated cosmetic procedures;

(f) easily removed by puncturing the membrane it develops and squeezing the material out; and

(g) having European Community approval.

The plaintiff, his physicians and the class members' physicians relied upon these representations in agreeing to Bio-alcamid injections.

16. In fact, Bio-alcamid:

(a) was not subject to any studies that would show *long term* safety and complications;

(b) causes infection months or years after injection;

(c) causes inflammation months or years after injection;

(d) is subject to significant migration months or years after injection;

(e) causes formation of granulomas months or years after injection;

(f) is not completely removed by puncturing and squeezing, may require repeat removal procedures including removal by way of a face lift and physically scraping the Bio-alcamid from tissue and bone and may ultimately not be completely removed;

(g) use of permanent fillers such as Bio-alcamid was criticized by expert organizations in Europe; and

(h) European Community approval deals only with manufacturing practices and does not relate to safety and suitability of the product itself.

17. The defendants knew or ought to have known that there were risks associated with the use of Bio-alcamid, that there were significant adverse reactions to this product, that they performed no long term safety research, and that the adverse reactions occurred in such a frequency and were of a serious nature so that utility of this cosmetic product was far outweighed by the risks.

THE REPRESENTATIVE PLAINTIFF

18. The plaintiff suffers from HIV related lipoatrophy. In August, 2006 the plaintiff had Bio-alcamid injected in his cheeks. By 2009 he had developed significant migration of the implanted material into his chin and neck, and severe infection and inflammation caused by the Bio-alcamid, accompanied by significant pain. In August, 2009 the plaintiff had a procedure which was able to remove only some of the implanted Bio-alcamid. In April, 2010 he underwent a full face lift, allowing the lifting up of the skin on the plaintiff's face, which was intended to allow the removal of remaining Bio-alcamid. The April 2010 procedure was unsuccessful and ultimate outcome and prognosis are not known at this time.

19. The plaintiff has suffered and will suffer pain and suffering, medical expenses and cost of care as a direct result of the implantation of the Bio-alcamid and the defendants' negligence and breach of statutes described above.

20. The plaintiff, his physicians and the class members' physicians were not warned of the risks associated with the use of Bio-alcamid. Had they been so advised he and the class members would have refused this medical product and would have

insisted on a safer alternative treatment or no treatment at all. But for the defendants' negligence and breach of consumer protection statutes they would not have suffered injuries and incurred damages.

21. The plaintiff and the class have incurred and will continue to incur expenses and special damages as a result of continued monitoring, care and treatment and possible removal of the Bio-alcamid.

22. The plaintiff and the class have suffered and will continue to suffer damages as a direct result of the defendants' negligence including, but not limited to, damages for the cost of implanting the Bio-alcamid, cost of removing Bio-alcamid, costs arising from future complications, pain and suffering and loss of enjoyment of life, loss of employment income and benefits, and other special damages and expenses.

Part 2: RELIEF SOUGHT

1. WHEREFORE the Plaintiff claims:

(a) an order certifying this proceeding and appointing him as representative plaintiff for the class and any appropriate sub-classes;

(b) general and special damages on account of, among other things, all medical and other expenses for testing, treatment and medical monitoring in such amount as is proved at trial;

(c) in the alternative to the claim for damages, payment of the revenues realized by the defendants from their sales of the medical devices known as Bio-alcamid;

(d) damages and/or an order returning monies obtained by the defendants to the class for deceptive acts or practices or unconscionable acts or practices under section 172 of the *Business Practices and Consumer Protection Act;*

(e) an interim and permanent injunction pursuant to section 172 of the *Business Practices and Consumer Protection Act* and other consumer protection statutes prohibiting the deceptive and unconscionable acts and practices committed by the Defendants;

(f) damages or other remedies under section 36 of the *Competition Act* (Canada);

(g) punitive, exemplary and aggravated damages;

Part 3: LEGAL BASIS

DUTY OF CARE ARISING FROM MANUFACTURE AND MARKETING OF MEDICAL DEVICES IN GENERAL AND COSMETIC MEDICAL DEVICES IN PARTICULAR

1. The defendants owed to the plaintiff and the class a duty of care:

(a) to ensure that Bio-alcamid was appropriately tested to determine whether there were any potentially adverse effects over the short and long term;

(b) to ensure that Bio-alcamid was fit for its intended or reasonably foreseeable use;

(c) to warn the plaintiff and the class that Bio-alcamid was subject to risks and significant adverse reactions

(d) to conduct adequate tests and clinical trials to determine the degree of risk associated with using Bio-alcamid;

(e) to ensure that physicians and surgeons and public (through their marketing materials intended for the public) were kept fully and completely informed of all risks associated with using Bio-alcamid or, as the case may be, of the fact that the risks were simply unknown because of the lack of long term research;

(f) to conduct ongoing tests and clinical trials with long term follow up to determine the long term effects and risks of Bio-alcamid;

(g) to monitor, investigate, evaluate and follow up on adverse reaction reports and research on the safety and utility of Bio-alcamid throughout the world;

(h) to monitor for full and true disclosure the information that each defendant has disseminated to the public and physicians concerning the risks, benefits and suitability of Bio-alcamid and to ensure dissemination of accurate information; and

(i) to properly inform Health Canada and other regulatory agencies of the risks associated with using Bio-alcamid.

2. Bio-alcamid is only used in elective, cosmetic procedures for which older, tried and true treatments are available. Because the plaintiff and the class did not undergo treatment with Bio-alcamid for any life or health threatening disease and there were other proven options for their treatment they should not be exposed to risks that might be acceptable when life or health threatening disease is being treated. The defendants should

therefore be held to the highest standard of design, formulation, safety testing and disclosure of risks.

DEFENDANTS NEGLIGENTLY BREACHED THEIR DUTY OF CARE

3. The defendants breached their duty of care to the plaintiff and the class as described above in the following respects:

(a) the defendants failed to conduct adequate tests and clinical trials initially and on an ongoing basis to determine the risks associated with the use of Bio-alcamid;

(b) the defendants manufactured, marketed, distributed and sold Bio-alcamid without adequately disclosing its risks, lack of long-term safety data and the content of recent research and personal experience of physicians retained by the defendants showing risks arising from use of Bio-alcamid;

(c) the defendants failed to give Health Canada complete and accurate information concerning Bio-alcamid by failing to disclose the risks known or that should have been known on a timely basis;

(d) the defendants failed to adequately warn the plaintiff, the class and their physicians and surgeons of the risks then known or which were reasonably foreseeable in using Bio-alcamid and failed to monitor the information other defendants were disseminating to ensure full and true disclosure;

(e) the defendants, with full knowledge that Bio-alcamid posed significant risks, failed to warn the plaintiff and the class and instead continued to sell, market and distribute Bio-alcamid throughout Canada;

(f) the defendants failed to adequately monitor, evaluate and act upon adverse reaction reports to Bio-alcamid in Canada and throughout the world;

(g) the defendants failed to establish any adequate procedures to educate their sales representatives and treating physicians and surgeons respecting the correct usage of Bio-alcamid and the risks associated with it;

(h) the defendants disseminated to physicians and the public lists of published research purporting to show short term safety of Bio-alcamid but did not disseminate lists of published research and other documents showing complications associated with Bio-alcamid.

4. The extent of the risks associated with Bio-alcamid was not known and could not have been known to the plaintiff, the class or their physicians. The injuries of the plaintiff and the class would not have occurred but for the defendants'negligence in failing to ensure that Bio-alcamid was safe for use and in failing to provide an adequate warning of the risks associated with it to the plaintiff, the class and their physicians.

5. In committing the foregoing acts, the defendants breached the *Food and Drugs Act*, R.S.C. 1985, c. F-27 and the *Medical Devices Regulations*, SOR/98-282, including, but not limited to, the following provisions:

(a) *Food and Drugs Act* (s. 20(1));

(b) *Medical Devices Regulations* (ss. 10-13: Safety and Effectiveness Requirements).

6. The defendants' conduct was unlawful because they knowingly marketed and sold Bio-alcamid and permitted it to be implanted into the class members. Despite knowing, or having reason to know, that the Bio-alcamid was defective, the defendants concealed the risks from the class members, health care providers, the medical community and regulatory authorities, including Health Canada.

7. The plaintiff pleads the *Negligence Act*, R.S.B.C. 1996, c 333 and similar statutes in other provinces set out in Schedule "A" hereto.

8. The plaintiff states that this claim may be served outside British Columbia pursuant to the *Court Jurisdiction and Proceedings Transfer Act*, S.B.C. 2003, Chapter 28 because it:

10(e) concerns contractual obligations performed in British Columbia;

(f) concerns restitutionary obligations that arose in British Columbia;

(g) concerns a tort committed in British Columbia; and

(h) concerns a business carried on in British Columbia.

LIABILITY UNDER *BUSINESS PRACTICES AND CONSUMER PROTECTION ACT* (BRITISH COLUMBIA) AND OTHER EQUIVALENT STATUTES IN OTHER PROVINCES AND *COMPETITION ACT* (CANADA)

9. The Plaintiffs and Class Plaintiffs are "consumers" under section 1 of the *Business Practices and Consumer Protection Act,* S.B.C. 2004 c. 2. ("BPCPA").

10. The defendants are "suppliers" under section 1 of the BPCPA.

11. Each purchase and injection of Bio-alcamid was a "consumer transaction" within the meaning of that term under section 1 of the BPCPA.

12. Each of the facts referred to in paragraphs 18 and 21 herein is a "material fact" within the meaning of the BPCPA.

13. The defendants engaged in deceptive and misleading acts and practices contrary to sections 4, 8 and 9 of the *Business Practices and Consumer Protection Act* (British Columbia) and false and misleading representations to the public contrary to section 52 of the *Competition Act*, R.S.C. 1985, c. C-34 by committing the acts described in paragraphs 18 and 21 herein. The defendants have unfairly and unjustly profited from these acts.

14. The defendants are liable for under other consumer protection statutes in Canada, all of which are set out in Schedule "B" hereto.

BASIS FOR LIABILITY OF THE PERSONAL DEFENDANTS

15. The Defendant Directors were responsible for, and they personally developed and implemented, the formulation, safety monitoring, advertising and marketing of Bio-alcamid. They personally committed the negligent acts and breaches of the consumer protection statutes referred to above in conjunction with the other defendants. As a result they are personally liable to the plaintiff and the class.

HEALTH CARE EXPENSES

16. All relevant provincial and territorial health insurers have incurred expenses with respect to the purchase of the Bio-alcamid and the medical treatment of the plaintiff and the class as a result of the defendants' negligence. Consequently, the health insurers have suffered and will continue to suffer damages for which they are entitled to be compensated by virtue of their right of subrogation in respect of all past and future insured services. This action is maintained on behalf of all provincial and territorial health insurers. The plaintiff specifically pleads the *British Columbia Health Care Costs Recovery Act.*

UNJUST ENRICHMENT AND WAIVER OF TORT

17. The defendants, as pleaded above:

(a) were aware since inception that Bio-alcamid had no long term safety data and entailed significant risks;

(b) from inception to the present date have concealed the risks associated with Bio-alcamid;

(c) failed to provide adequate warnings to the class about the risks associated with Bio-alcamid;

(d) continued to sell Bio-alcamid after evidence of the risks and associated injuries came to their attention; and,

(e) continued to profit from this wrongful behaviour.

18. The plaintiff and the class have suffered a detriment as set out in paragraphs 22-23 of Part 1 herein and the defendants have obtained a benefit without juristic reason.

19. The plaintiff and the class plead that the defendants have been unjustly enriched as a result of the revenues generated from the sale of Bio-alcamid.

20. The plaintiff and the class plead in the alternative to their claim for damages they are entitled to "waive the tort" claim in negligence and instead elect to claim payment of the revenues generated by the defendants as a result of their failure and refusal to properly bring the risks associated with Bio-alcamid to the attention of the plaintiff and the class.

21. The plaintiff claims punitive, exemplary and aggravated damages as a result of the egregious and outrageous conduct of the defendants and, in particular, their callous disregard for the health and lives of vulnerable patients in Canada. In particular, the defendants' conduct in continuing to manufacture, market, sell and distribute Bio-alcamid after obtaining knowledge it was not performing as represented and intended, shows complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages in such a sum that will serve to deter the defendants from similar conduct in the future.

22. The defendants committed various independent actionable wrongs including:

(a) minimizing and understating the risks of Bio-alcamid;

(b) positively promoting and marketing Bio-alcamid while withholding relevant information about the risks as set out above; and

(c) failing to disclose the risks to the class members and their physicians and to the regulatory authority, Health Canada, in violation of the *Food and Drugs Act*, R.S.C. 1985, c. F-27, and the *Medical Devices Regulations*, SOR/98-282.

Plaintiff's address for service:

Bruce W. Lemer
Associate Counsel, Grant Kovacs Norell
400 – 900 Howe Street
Vancouver, BC V6Z 2M4

Fax number address for service (if any): (604)609-6688

Email address for service (if any): N/A

Place of Trial: Vancouver, BC

The address of the registry is:

Law Courts, 800 Smithe Street
Vancovuer, BC V6Z 2M4

Place of trial: Vancouver, BC

Date: April 1, 2011

Signature of Bruce W. Lemer

[ ] plaintiff [X] lawyer for plaintiff

Rule 7-1 (1) of the Supreme Court Civil Rules states:

(1) Unless all parties of record consent or the court otherwise orders, each party of record to an action must, within 35 days after the end of the pleading period,
    (a) prepare a list of documents in Form 22 that lists
        (i) all documents that are or have been in the party's possession or control and that could, if available, be used by any party at trial to prove or disprove a material fact, and
        (ii) all other documents to which the party intends to refer at trial, and
    (b) serve the list on all parties of record.

APPENDIX

Part 1: CONCISE SUMMARY OF NATURE OF CLAIM:

Claim for negligence and breach consumer protection statutes in the manufacture, sale and marketing of a medical product.

Part 2: THIS CLAIM ARISES FROM THE FOLLOWING:

[] a motor vehicle accident

[ ] medical malpractice

[ ] another cause

A dispute concerning:

[ ] contaminated sites

[ ] construction defects

[ ] real property (real estate)

[ ] personal property

[x] the provision of goods or services or other general commercial matters

[ ] investment losses

[ ] the lending of money

[ ] an employment relationship

[ ] a will or other issues concerning the probate of an estate

[ ] a matter not listed here

Part 3: THIS CLAIM INVOLVES:

[X] a class action

[ ] maritime law

[ ] aboriginal law

[ ] constitutional law

[ ] conflict of laws

[ ] none of the above

[ ] do not know

Part 4:

Business Practices and Consumer Protection Act, S.B.C. 2004, c. 2 and similar statutes in other Provinces listed in Schedule A

Competition Act, R.S.C. 1985, c. C-34

Health Care Costs Recovery Act and similar provincial health care costs recovery statutes

Court Jurisdiction and Proceedings Transfer Act, S.B.C. 2003, Chapter 28

This NOTICE OF CIVIL CLAIM is filed by BRUCE W. LEMER, Associate Counsel, Grant Kovacs Norell, whose place of business and address for service is #400 – 900 Howe Street, Vancouver, BC, V6Z 2M4, Fax: (604) 609-6688. [File: 1788-003].